JUL 13 2006

Premarket Notification 510(k) Summary

(per 21 CFR 807.92)

Coramate/Spirotome System

1. Submitted by:

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Date prepared: April 4, 2006

2. Device Name:

Trade Name: Coramate/Spirotome system
Classification Name: Biopsy Needle

3. Predicate Device:

The Mammotome Biopsy System (K033700) is substantially equivalent to other biopsy needle systems on the market, including the Coramate/Spirotome system.

4. Device Description:

The Coramate/Spirotome system is a mechanical biopsy device to harvest soft tissues from the human body, in particular from the female breast to detect and confirm malignant cells in the earliest phase of progression.
The Coramate/Spirotome system consists of 2 major components: the set of needles (Spirotome) and a powered device that operates the needles (Coramate). The set of needles can be operated manually as well (single-use and reusable Spirotome).
The needle set contains 3 needles that work in conjunction. The trocar needle brings the cutting cannula up to the diseased site. The receiving needle, with a helix at the top, penetrates the diseased area, and the cutting cannula frees the sample from the surrounding tissues.
The following accessories are optionally provided with the system e.g. releasing element, needle spacer and needle protecting tube.

5. Intended Use

The Coramate/Spirotome system is intended for diagnostic sampling of breast tissue during breast biopsy procedures. It is to be used for diagnostic purposes only and is not intended for therapeutic uses.

The Coramate/Spirotome system is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

6. Technological Characteristics

The Coramate/Spirotome system is equivalent to the currently marketed vacuum assisted powered macrobiopsy systems, including the Mammotome (K033700). It contains a needle set and a hand held powered device. In addition, it has the same intended use.
The basic system is a radial cutting of a cutting cannula on a helicoidal shaped receiving element. This system can be operated manually, whereby the system is advanced by the aid of a trocar needle. Combined, this needle set is called the Spirotome and can be delivered single-use or as a reusable device.
The Coramate is a powered device that operates the same needles automatically. The interface with the patient is the same both in the Coramate and Spirotome: i.e. the needle set. In addition, the Coramate includes a vacuum to the needles for maximal performance.
The Coramate contains a combination of interfaces, motors and software in addition to a battery with loader. The interfaces fix the needle set into the device. The 4 small motors perform the necessary movements of the needles. The software guides the motors into smooth and ordered movements of the needles. The batteries power the device.
Accessories may be added to the system: e.g. releasing element, spacer, protecting ring, and battery loader.
The technological differences between the Coramate/Spirotome and the predicate device were introduced to improve performance and safety.

7. Performance data

Thorough preclinical testing was performed to ensure the device performs as intended. In particular most laboratory and preclinical testing was done on animal breast tissues to ensure maximum performance in the human situation.
Clinical testing indicates that all performance and safety aims are reached. Since the interface of the system is the same in the Spirotome compared to the Coramate, all the clinical evidence gained by the Spirotome is relevant to the Coramate. Most of the clinical work has been done in human breast tissues as has been published in international PEER reviewed Journals and Meetings. In addition, recent clinical evidence is added relating only to the Coramate. In summary, all this clinical data indicate that the Coramate and Spirotome perform as intended, with aimed performance and maximal safety and similar to the predicate device. In particular, no complication was noted up to now in the clinical tests and subsequent vigilance quality control follow-up.
The Spirotome device complies with the European Medical Device Directive 92/42/EEC.
The Coramate device is submitted for approval in the European Community and

approval is pending. All requested standard testing according to the claims made have been done.

8. Conclusion

Based upon the testing and comparison to the predicate device, the Coramate/Spirotome system has the same intended use with similar technological characteristics as the predicate devices. The system performs as intended and raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JUL 13 2006

Re: K060384
Trade/Device Name: Coramate/Spirotome System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: June 19, 2006
Received: July 6, 2006

Dear Ms. Buttiens:

This letter corrects our substantially equivalent letter of May 10, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

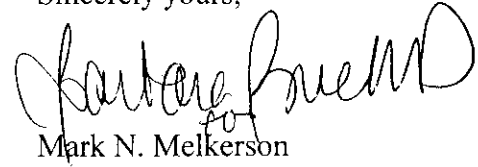
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):
K 060384

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Prescription Use ____X____ **AND/OR** **Over-The Counter Use**_____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINU ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060384